REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejection of all the claims now in the application (i.e. Claims 1-30) is respectfully requested in view of the foregoing amendments and the following remarks.

In the final Office Action, the Examiner objected to claim 26 for failing to further limit the subject matter of claim 1. Applicant has amended claim 26 to recite that the physical cross-linking is done by a freezing-thawing technique.

The Examiner then went on to reject method claims 1, 21 and 24-26 as being anticipated by *Stoy et al.* U.S. Patent No. 5,149,052. Applicant has amended method claim 1 to require that the equilibrium hydrogel crystallinity be adjusted to ensure that the swelling pressure of the hydrogel remains stable after implantation by washing the molded gel in a solution containing both sodium and potassium ions. As set forth in column 6, lines 64-66 of *Stoy et al.*, after the gelation of *Stoy* is complete, the mold is opened and the residual solvent is washed from the molded hydrogel product in the open mold. No solution is specified, however, even if a saline solution was used, there is no teaching to adjust the hydrogel crystallinity using the solution nor utilizing potassium and carbonate ions in this process. Thus, it is applicant's position that *Stoy et al.* does not anticipate amended claim 1.

The Examiner went on to reject claims 2-4, 8 and 11 as being obvious over *Stoi et al.* in view *Refojo* U.S. Patent No. 4,452,776. *Refojo*, in column 5, lines 9-12 teaches using water to wash the hydrogel. Applicant submits, since *Stoy et al.* in column 6, lines 64-66 teaches no washing solution, that a combination of *Stoy et al.* and *Refojo* would merely teach washing the residual solvent from the molded hydrogel with water. Again, neither reference suggests a solution with sodium carbonate, chloride and potassium ions as presently claimed in claim 1. *Refojo*, in column 7, lines 15-17, suggests the use of a physiological saline solution to hydrate the implant not to change the crystallinity. The Examiner considers that *Refojo*, in column 4, lines 11-16, teaches a method where dehydration reduces the water content to its in-vivo equilibrium water content as claimed. However, *Refojo* does not teach or suggest dehydrating the implant to its equilibrium water content but merely states that a dehydrated implant typically absorbs about 15% to 70% by weight of water in its hydrated state. There is no connection between what is described and a dehydrating the implant to in-vivo step prior to packaging as claimed in the combination of claim 8.

Furthermore, applicant has amended method claim 1 to make it clear that the

washing in the solution containing sodium, carbonate, chloride and potassium ions is for adjusting the hydrogel crystallinity to ensure that the swelling pressure of the hydrogel remains stable after implantation. Washing in pure water as taught by *Refojo* would not have any effect on the crystallinity regardless of the length of time the washing occurred. Obviously, the time necessary to remove impurities with water has no bearing on the washing time in the ionic solution necessary to ensure that the swelling pressure of the hydrogel remains stable after implantation. Consequently, applicant considers amended claim 1 to be non-obvious and the claims dependent from claim 1 to be patentable.

The Examiner went on to reject claims 5-7, 9-10 and 13-20 as being unpatentable over *Stoy et al.* and *Refojo* further in view of *Molock et al.* U.S. Patent No. 5,681,871. The Examiner considers that *Molock et al.* carries out a process wherein the saline solution further contains a potassium carbonate solution. In this regard, the Examiner cites column 7, lines 54-60, which refer to Example 11 of *Molock et al.* In Example 11, the molds were washed for three hours at 70°C to remove the inert dilutent and any residual unreacted monomers using a physiological saline solution. The contact lenses were then hydrated in a 2 weight percent aqueous solution of potassium carbonate at 50°C for 60 minutes. Thereafter, the lenses were rinsed in physiological saline at 50°C for 15 minutes. The lenses were then allowed to equilibriate in fresh saline at 35°C for three hours. There is no teaching in Example 11 that a single solution containing sodium, carbonate, chloride and potassium ions should be used as the washing solution to adjust crystallinity. By washing the molded material of *Molock et al.* for 3 hours in physiological saline, the hydrogel is driven toward a first equilibrium crystallinity. Thereafter, placing the hydrogel in a 2 weight percent aqueous solution of potassium carbonate at 50°C for 60 minutes drives the equilibrium crystallinity of the hydrogel towards a second point different from the first point. After that hydration, using physiological saline to wash the lenses for 3 hours, again drives the equilibrium crystallinity towards the first point. There is no teaching or suggestion of using a single solution with potassium, carbonate, chloride and sodium ions to drive the crystallinity towards a point that ensures that the swelling pressure of the hydrogel remains stable after implantation as now claimed in all the independent claims in the application. It should be noted that the Examiner continually indicates that the motivation in combining the various references is to make the washing solution more compatible with human fluid. As stated in applicant's specification, in paragraphs 19, 20 and 36, the use of potassium and carbonate ions effects the rate at which the PVA hydrogel will reach its equilibrium

crystallinity and therefore ensuring the swelling pressure characteristics of the material used in the artificial nucleus implant would remain stable after implantation. This has nothing to do with biocompatibility. Furthermore, the art cited by the Examiner in the rejections under 35 U.S.C. § 103 all relate to contact lenses where the swelling pressure is immaterial.

With regard to claims 9 and 10, applicant has limited the claims to gamma irradiation to distinguish over use of ultra-violet radiation. Note, claim 10 now depends from claim 9. With regard to claim 10, applicant is unclear as to how the language of *Molock et al.* quoted on column 6, lines 5-9 makes it obvious to irradiate the hydrated gel since the quoted language merely requires the application of a UV absorbing agent to the polymer and thereafter hydrating the lens. There does not appear to be any suggestion of irradiating the lens prior to packaging the implant.

With regard to claim 27, the Examiner believes it would be obvious to one of ordinary skill in the art to include *Molock et al's* potassium carbonate in *Stoy et al.'s* washing solution. As pointed out above column 6, lines 64-66 of *Stoy et al.*, teach no washing solution composition and even if *Stoy et al.* were to use a saline solution, there is no incentive to then include a potassium carbonate in the washing solution since there would be no advantage to have carbonate and potassium ions in a solution designed to wash residual solvent from the molded hydrogel product in the open mold.

With regard to claims 15 and 16, there is no suggestion in *Stoy et al.* of how long washing should occur. Applicant considers that the prior art cited by the Examiner uses washing to remove residual solvent or monomer and not to effect the crystallinity of the hydrogel structure. Therefore, one skilled in the art would learn nothing of the wash time for equilibrium crystallinity from the several week time frame necessary to remove the copolymer of *Refojo* from the mold.

Again, with regard to claim 19, applicant does not believe that there is any suggestion in either *Refojo* or *Stoi et al.* or *Molock et al.* to utilize a washing solution containing sodium, chloride, potassium and carbonate ions to adjust the hydrogel equilibrium crystallinity to ensure that the swelling pressure of the hydrogel remains stable after implantation. As stated above, in the contact lens art, the swelling pressure is not of concern. Thus, it is applicant's position that one of ordinary skill in the art would not consider a contact lens to be a medical implant as claimed and would not consider the contact lens art to be analogous art since it is not pertinent to the swelling pressure problem being solved. See *In Re Oetiker* 24 USPQ2d1443.

Again, with regard to claim 29, applicant has limited the irradiation to gamma irradiation and consequently, applicant does not believe it would be obvious to one skilled in the art to irradiate a molded gel after washing in order to test its durability in environments having radiation since there is no medical implant expose to gamma ray irradiation during use.

In addition, with regard to independent claim 27 and various dependent claims throughout the application, the Examiner indicates that *Stoy et al.* teaches forming a hydrogel from a polymer solution by physically cross-linking the polymer solution to form a semi-crystalline gel using a freeze-thawing technique set forth in column 12, lines 39-42. Lines 39-42 indicate that the mold containing the solution was immersed in a chilled water at a temperature of 5 to 10°C. Obviously, this temperature is well above the freezing point and, in fact, the solution discussed in Example 2 does not freeze until 0°C. Applicant considers claim 27, as amended, to distinguish over the art cited for the reasons discussed above.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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